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The Effect of Using Water-based Gel Lubricant During a Speculum Exam On Pap Smear Results

Abstract

Background: Cervical cancer is a pervasive yet preventable killer. Although routine screening exams are available to aid in the early detection of cervical cancer, women often avoid getting their routine annual screening exams. One explanation of this could be due to the discomfort of speculum exams. One way to minimize the discomfort of the speculum exam is to use gel-lubricant. However, there is much debate about whether lubricant obscures pap smear results or not.

Methods: Literature search conducted using MEDLINE-Ovid, JAMA, CINAHL (EBSCOhost), Evidence-Based Medicine Reviews Multifile and Evidence-Based Resources from the Joanna Briggs Institute using the following search terms: cervical and lubricant, Pap smear and lubricant. Bibliographies of research articles were searched for additional articles. The inclusion criteria were randomized control trials and cohort studies and included articles where women were receiving routine pap smears, providers were using pap smears that were collected using slide fixative or using liquid-based pap smear collection and using water-soluble gel lubricant. Women of all ages and fertility status were included.

Results: Searches yielded seven articles that were related to the clinical question. Six of seven articles found no statistically significant difference in the rate of unsatisfactory cervical cytology samples between water lubricant and gel-lubricant. Two of those six articles also found no difference in the ability to recognize LSIL, HSIL, ASCUS, or AGCUS in gel-contaminated samples. One article found a statistically significant increase in the number of unsatisfactory samples in the experimental group. They also found that the diagnosis of insidious pathology was missed in the experimental group.

Conclusion: The use of water-based gel lubricant does not increase the rate of unsatisfactory slides and does not inhibit the ability to recognize LSIL, HSIL, ASCUS or AGCUS specimens. These findings suggest that the use of lubricant may help to increase patient adherence to these screening recommendations while not compromising test accuracy. However, the literature suggests that too much lubricant could increase the rate of satisfactory slides and potentially cause the pathologist to miss a more insidious pathology. Ultimately, the potential for minimizing discomfort, and increasing patient compliance far outweighs the cost of lubricant that clinics may incur.

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The Effect of Using Water-based Gel Lubricant During a Speculum Exam On Pap Smear Results

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A Clinical Graduate Project Submitted to the Faculty of the

School of Physician Assistant Studies

Pacific University

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Faculty Advisor: Mark Pedemonte, MD

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and

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Biography

[Redacted for privacy]

Abstract

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Keywords: cervical and lubricant, Pap smear and lubricant

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List of Abbreviations

LSIL: Low-grade squamous intraepithelial lesion

HSIL: High-grade squamous intraepithelial lesion

ASCUS: atypical squamous cells of undetermined significance

AGCUS: atypical glandular cells of undetermined significance

ASC-H: atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion

USPSTF: United States Preventative Services Task Force

The Effect of Using Water-based Gel Lubricant During a Speculum Exam On Pap Smear Results

BACKGROUND

According to the American Cancer Society, approximately 12 200 new cases of cervical cancer will be diagnosed this year and approximately 4210 women will die from cervical cancer.{{27 American Cancer Society 2010; }} Although these numbers are staggering, there has been a marked improvement in early detection with the advent of the pap smear as a screening exam.{{28 American Cancer Society 2010; }} Despite the many benefits of routine pap smear screenings and the sensitivity of our tests in helping with early detection of cervical cancer there are still many women who do not get regular screening pap smears. There are a myriad of reasons why women do not get routine pap smears. Some of these reasons might include a lack of health insurance, a lack of health education, cultural barriers, lack of money, transportation issues, discomfort or anxiety to name a few. Medical providers are not able to address all of these issues, however, the onus is on medical providers to try and minimize a patient's discomfort and aversion to participating in preventative health measures. One of the ways that providers can improve patient compliance with routine pap smears is by using lubricant during speculum exams. If this issue could be addressed in some way without affecting the accuracy of the test, then every effort by medical providers should be made to do so. This issue is important because cervical cancer is a debilitating illness that affects thousands of women annually. It is also an illness that is relatively preventable provided that women get routine annual screening exams.

Currently, the U.S. Preventative Services Task Force recommends beginning screening for cervical cancer once a woman is eighteen, or once she become sexually active.{{29 Agency for Healthcare Research and Quality 2003; }} Research conducted by the USPSTF recommends screening once every three years however,{{29 Agency for Healthcare Research and Quality 2003; }} the current widespread clinical practice is to screen annually once a woman is sexually active or eighteen years of age. Screening continues until the age of sixty-five, provided that a woman does not have additional risk factors for cervical cancer.{{29 Agency for Healthcare Research and Quality 2003; }} In

most clinical practices, speculum exams are performed using either tap water as a lubricant, or a water-soluble gel based lubricant and pap smears are collected using a water-based medium such as Thinprep or SurePath.

This literature review aims to help clarify whether the use of gel-lubricant during a speculum exam obscures cytological results, thus causing clinical harm at the expense of alleviating discomfort.

METHODS

An exhaustive literature search in MEDLINE-Ovid, JAMA, CINAHL (EBSCOhost), Evidence-Based Medicine Reviews Multifile and Evidence-Based Resources from the Joanna Briggs Institute was conducted using the following search terms: pap smear and lubricant, cervical and lubricant. Bibliographies of research articles were searched for additional articles.

Inclusion criteria for the search included randomized control trials and cohort studies. Also included were articles in which women had routine pap smears collected using slide fixative or using a liquid-based pap testing and water-soluble gel lubricant. Women of all ages and fertility status were included. Articles that did not compare the results of lubricant use with a control were excluded or articles that measured lubricant use obscuring results other than pap smear results were excluded.

A critical appraisal of each of the articles was performed to assess the validity of each article. A modified Jadad was applied to each article. The Jadad score was modified because in this case patients could not be lost to drop out, so one point was added to the Jadad score if the study described in their methods if patients were informed and if they were allowed to decline participation in the study.

Results

A literature search yielded eight articles that were related to the clinical question. However, one article only served as background information, which left only seven articles to analyze.

The first article reviewed, was written by Hathaway et al {{26 Hathaway,J.K. 2006; }} . The article, titled “Is Liquid-Based Pap Testing Affected by Water-Based

Lubricant?” is a randomized controlled trial. In this study a group of 200 women who were getting routine speculum exams was analyzed. Two samples from each participant in the group were obtained, and after randomly assigning half of the specimens to the experimental group, they contaminated each experimental sample with 0.5 ml of water-based lubricant. All samples were collected in the same manner. All cervical cytology was collected first with a spatula, and then an endocervical brush. All samples were then analyzed by one group of cytopathologists. Most of the samples were analyzed by two pathologists, and when the results of the samples differed between the control and the experimental, an additional pathologist analyzed the sample. Both the physicians collecting the samples, and the cytopathologists were blinded to which samples received the experimental treatment. Specimens were found to be identical in 185 out of 200 women. In the 15 inconsistent samples, there was one sample that read normal, where its counterpart read abnormal. This occurred in both the experimental and the control group. In the intervention group there were three samples where the results were normal, but the control group showed ASCUS and two where it showed ASC-H and one where the control had unsatisfactory results. Of the diagnosis of ASCUS in the intervention groups there were two that were read as normal in the control group, two that were LSIL and one that was ASC-H. Of the experimental results that were read as LSIL, there were two that were read as normal in the control group. In one experimental sample that was read as HSIL, its counterpart was read as ASC-H. In one experimental sample that was classified as “unsatisfactory”, its control was read as normal. There was a similar rate between intervention and control groups of abnormal cell cytology, with 6.5% and 7.0% respectively. There was no statistical difference between groups when analyzed for insufficient number of endocervical cells within the sample {{26 Hathaway,J.K. 2006; }}.

The second study was done by Griffith et al {{24 Griffith,W.F. 2005; }} and is described in a paper titled “Vaginal Speculum Lubrication and its Effects on Cervical Cytology and Microbiology”. A randomized control trial was performed on women receiving routine gynecological examinations. Researchers assigned a number of clinics to either a water only or water-soluble gel intervention for a period of one month by random computer generation. The trial was performed for a period of eight months. All

paps were collected using an Ayres spatula followed by an endocervical brush. When clinics performed speculum exams during the month where they were to perform them using lubrication, they were instructed to apply a dime sized portion of lubricant to the distal, exterior surface of both the top and bottom blades. There were a total of 3460 pap smears collected during this time with 1828 pap smears collected during the months where lubrication was being used and 1632 pap smears collected during the months where water only was being used. Pap smears were analyzed by one group of pathologists who were blinded to which samples they were analyzing. During the experiment, the months where lubricant was used, they found that the unsatisfactory rate was 1.1%, and in the water lubricant period, the unsatisfactory rate was 1.5%. The odd's ratio calculated for gel-lubricant versus no lubricant obscuring pap smear results was 0.74, with a 95% confidence interval (0.41-1.35) {{24 Griffith,W.F. 2005; }}.

The third article titled “Does Gel Affect Cytology or Comfort in the Screening Papanicolaou Smear?” written by Gilson et al {{23 Gilson,M. 2006;}} is a RCT that includes women 18 years and older receiving regular screening pap smears. In this study they excluded women who were being seen for a specific gynecological complaint, did not have a cervix, were opposed to pap smears in general and who had chronic pelvic pain. The women in this study received two pap smears with two specula. The patients were split into two groups using computer-generated randomization. In the experimental group the first exam was performed with a dry speculum and the second exam was performed with 2.7 g of water-based lubricant applied to the external portion of the speculum blades. The control group received two speculum exams using a dry speculum. Both groups had their pap smears collected in the same fashion. First, they used a large cotton tipped swab to clear away excess mucous, then they used a spatula followed by an endocervical brush to collect endocervical cells. All cervical samples were analyzed by the same group of cytotechnologists. All cytotechnologists were blinded to whether they were analyzing the treatment group or the control group. A total of 70 pap smears were collected. Because the sample size was so small, a Fisher exact test was used to analyze the groups. There was found to be no statistical significance between groups in the proportion of unsatisfactory slides. The slides that were labeled as unsatisfactory (two slides) were labeled this due to obscuring amount of blood on the slide, and from poor

fixation by the person preparing the slide and were not due to the use of gel-lubricant {{23 Gilson,M. 2006; }}.

The next article written by Harer Jr. et al {{21 Harer,W.B. 2002; }} titled “Lubrication of the Vaginal Introitus and Speculum Does Not Affect Papanicolaou Smears” conducted a randomized control trial with 200 women who were receiving regular screening pap smears. Participants were randomized into an experimental group and a control group using computer-generated randomization. The control group was given speculum exams using water as lubricant. The experimental group had 2-3 cc of water-based lubricant applied to the introitus with a gloved finger before placing a lubricated speculum. Both groups had their cervical cytology specimens collected using first, an Ayres spatula, and then second using an endocervical brush. The cytotechnologists who analyzed the slides were blinded to whether they were analyzing the experimental group or the control group. When the slides were analyzed, there was no gross lubricant seen on the slides. Also in this study they found an extremely low rate of unsatisfactory slides in both the control and the experimental groups (2.1% and 2.2%, respectively). After statistical analysis the study claimed that they would need to have 10,000 participants in the study to detect a statistically significant unsatisfactory rate therefore the study was closed {{21 Harer,W.B. 2002; }}.

An article written by Charoenkwan et al {{17 Charoenkwan,K. 2008; }} titled “Effects of Gel Lubricant on Cervical Cytology” reports a randomized control trial in which women who were receiving regular screening pap smears participated. In this study women were analyzed according to their reproductive status and women who did not have a cervix, who were actively bleeding, who had received pelvic radiotherapy, who had been using intravaginal medications and women who were allergic to lubricant were excluded from the study. There were 1334 participants who underwent speculum exam using water as a lubricant. Two samples were collected, both using first an Ayres spatula, however, after the first sample was collected, a 1-1.5 cm stripe of lubricant was applied to a large cotton tipped swab which was then applied to the cervical os, then a second sample was collected with the Ayres spatula. The samples were both analyzed by one pathologist who was blinded to which samples were the control and which were the experimental samples. During the analysis samples were considered unsatisfactory if they

contained less than 8000 well preserved endocervical cells or if greater than 75% of the cells were obscured by inflammation, blood, artifact, gel, etc. The findings of this study were that the gel containing samples had a significantly higher unsatisfactory rate compared to their controls (12.1% compared to 1.7%). The unsatisfactory results in the experimental groups were all due to an insufficient amount of endocervical cells contained on the slides. When the samples were compared to one another, their adequacy rate matched in 87.3% of the samples. The remaining samples showed that 11.5% had inadequate samples in the gel-containing samples, whereas the control samples were adequate, however in 1.1% of the samples the control was inadequate but the gel-containing samples were adequate. In the samples that were considered satisfactory for analysis, 65.2% had a relatively close numbers of cells, however the control groups had consistently higher number of cells in the sample at a rate of 31.8%. The gel-containing group had a higher number of cells in the sample 3% of the time. In 23.4% of the slides, the gel was grossly visible, however, the gel did not interfere with the ability to read the slides. There was only a 0.3% disagreement in the diagnosis when gel-containing slides were compared to the controls, however, there was one case of LSIL, ASCUS and squamous cell carcinoma each were missed in the gel-containing samples {{17 Charoenkwan,K. 2008; }}.

In an article titled “Water Versus Gel Lubricant for Cervical Cytology Specimens” Tavernier et al {{19 Tavernier,L.A. 2003; }} reported a cohort study where they reviewed 4169 pap smears from medical records. Of those 4169 pap smears they selected every sixth chart and found 615 samples that had enough information in the medical record to be analyzed in their study. The medical records included various information, including whether the samples collected were adequate or not, whether they were obscured, and whether gel or water lubricant was used. Results indicated that there was no difference in the adequacy of the sample, or in the rate at which samples were considered obscured, between gel-lubricant groups, water lubricant groups and no lubricant groups. There was less obscuration in the water lubricant group (3.2%) compared to gel lubricant or no lubricant (6.2%, 6.5%), however the difference was not found to be statistically significant {{19 Tavernier,L.A. 2003; }}.

An article titled “The Effect of Vaginal Speculum Lubrication on the Rate of Unsatisfactory Cervical Cytology Diagnosis” was written by Amies et al {{20 Amies,A.M. 2002; }}. This study was a randomized control trial, where a number of clinics were randomly assigned a period of time to use water-soluble gel lubricant or to use water only lubricant during the intervention time. Women who were at the clinic to receive a regular screening pap smear were included in the study. The clinicians in the experimental group were instructed to place a dime-sized amount of gel lubricant to the exterior, end of the speculum blades before performing the speculum exam. The control group was instructed to lubricate with tap water. Both groups collected endocervical samples by first using an Ayres spatula, followed by an endocervical brush. Samples were applied to a slide and then fixed. Both clinics used the same group to analyze samples and used the same vendors for their cervical cytology collection supplies. Cytopathologists were blinded to which groups they were analyzing. A total of 8534 pap smears were collected from five clinics during the intervention period. Findings indicated that the frequency of ASCUS, LSIL, HSIL, and AGCUS did not differ with any significance between the control groups and the experimental groups. They also analyzed the clinics’ rates against themselves compared to prior to the experiment and after the experiment and found that the rates of unsatisfactory results, ASCUS, LSIL, HSIL and AGCUS did not differ significantly within groups. Cytopathologists did not report any obscured results due to gel overlay. Unsatisfactory results were typically due to excess inflammation, excessive blood, or not enough cells in the sample to make a diagnosis. The rates of unsatisfactory samples did not differ between groups {{20 Amies,A.M. 2002; }}.

DISCUSSION

There is widespread variability among providers and between clinics about whether to use lubricant during pap smears or not. It is understandable that there would be such variability, considering that there is a lot of confusion about whether the use of lubricant would obscure cervical cytology results or not. With cervical cancer claiming thousands of women every year, the medical community is very hesitant to use any intervention that would lessen the chances of adequately screening for this insidious

illness. Surprisingly, even though there is so much discord in the medical community about whether to use lubricant during pap smears, the research is pretty clear. The majority of the articles reviewed indicated that there was no difference in the frequency of unsatisfactory results when it came to using water-based gel lubricant during a routine, screening pap smear. There also seemed to be no difference when it came to diagnosing ASCUS, LSIL, HSIL and AGCUS. There is one article written by Charoenkwan et al {{17 Charoenkwan,K. 2008; }} that got results that differed from the findings of all the other papers. They found that there were significantly more unsatisfactory results when gel-lubricant was used. They also found that using gel made it so that diagnosis of squamous cell carcinoma, LSIL and ASCUS was missed. However, in the aforementioned study, they applied gel lubricant directly to the os before collecting the sample. {{17 Charoenkwan,K. 2008; }} In the studies where lubricant was used in the more conventional method, or when lubricant was applied directly to the specimen, the results consistently did not indicate a difference in the cervical cytology between lubricant and non-lubricant contaminated specimens. The results of the study performed by Charoenkwan et al {{17 Charoenkwan,K. 2008; }} suggest that the use of too much lubricant may in fact obscure results. However, all the other articles found indicate that when lubricant is applied to the introitus and/or directly onto the speculum, water-based gel lubricant does not obscure cervical cytology results.

Most of the studies were designed very well. Most of them used randomization to put their groups into experimental versus control groups. Most of the studies blinded the pathologists to which specimens they were evaluating. There was variability in how the gel-lubricant was applied. In the studies where two specimens were collected, they either applied gel directly to the cervical os, contaminated the sample with gel, or performed two speculum exams on the same patient, one using gel-lubricant and one without. Even though there was variability in the way the intervention was conducted for the experimental groups, it did not seem to affect results for the most part. The only study where the design did not seem to directly correlate with real world application was the one conducted by Charoenkwan et al {{17 Charoenkwan,K. 2008; }}. Applying gel directly to the cervical os, rather than to the specimen, the speculum or to the introitus would likely produce an increased amount of samples without an adequate amount of

cervical cells, which is indeed what the results indicated. The study performed by Hathaway et al {{26 Hathaway,J.K. 2006; }} describe in their methods section that majority of the slides were read by two pathologists, and when the slides differed a third pathologist read them. However, they do not indicate in the methods section how many slides were included in this majority, which would make it difficult to reproduce the study as it is described. They also do not clearly define what they consider to be “unsatisfactory” results, which makes their results difficult to interpret{{26 Hathaway,J.K. 2006; }}. The study performed by Griffith et al{{24 Griffith,W.F. 2005; }} talks about how the frequency of unsatisfactory slides in the experimental group was similar to what normally occurred. However, the authors do not establish clearly how they calculated the clinic’s “normal” frequency of unsatisfactory results. They also randomize entire clinics to either an intervention group or control group for a certain period of time. This would allow for a lot of bias since it would be quite obvious to the clinicians which part of the experiment they were participating in at any given point in time {{24 Griffith,W.F. 2005; }}. In the study performed by Gilson et al {{23 Gilson,M. 2006; }} their exclusion criteria excluded women who had a primary gynecological complaint. Arguably this could decrease their rate of unsatisfactory results by excluding samples with inflammation or other abnormal results due to a primary gynecological pathology such as infection or cancer.

An important flaw of all the research is that, except for one study, all the cervical cell samples were collected, and fixed on a slide for analysis. Most of the pap smears are currently being collected using a liquid based pap, such as Thinprep. The study conducted by Hathaway et al {{26 Hathaway,J.K. 2006; }} looked specifically at how the use of lubricant would obscure liquid-based pap smears. The results of this study could arguably, be more generalized than the studies where the cells were analyzed from fixed slides.

CONCLUSION

Although there is much debate among clinicians about whether to use lubricant or not, it appears that the debate is largely based on bias and not research. Women frequently site discomfort as a reason for not getting annual screening pap smears.

Considering the burden that cervical cancer has on the medical system, and the morbidity and mortality cervical cancer causes to the patient, we should try to minimize the discomfort as much as possible. One way that medical professionals could minimize the discomfort of an annual screening pap smear is to use lubricant during speculum exams. This intervention is relatively inexpensive, particularly compared to cervical cancer and causes a negligible amount of inconvenience to the medical provider. However, like most things in life, all good things must be used in moderation. The results of some of the research suggest that too much lubricant during speculum exams could increase the rate of unsatisfactory results and even cause harm by certain diagnosis being missed. The results of this literature search suggest that using water soluble gel-based lubricant during pap smears could minimize patient discomfort and increase patient compliance without obscuring results, provided it is done in moderation. There needs to be more research on whether gel-lubricant obscures pap smear results when using a liquid-based medium such as Thinprep or SurePath since these are now the most common forms of pap smear collection. There also needs to be more research about how much lubricant is an appropriate amount and at what threshold does the amount of lubricant become too much, thus obscuring pap smear results. Research on these parameters might better guide clinicians in the appropriate use of gel-lubricant.

REFERENCES

1. American Cancer Society. What are the key statistics about cervical cancer? Available at: <http://www.cancer.org/Cancer/CervicalCancer/DetailedGuide/cervical-cancer-key-statistics>. Accessed 07/20/2010, 2010.
2. American Cancer Society. What is cervical cancer? Importance of cervical cancer screening. Available at: <http://www.cancer.org/Cancer/CervicalCancer/MoreInformation/CervicalCancerPreventionandEarlyDetection/cervical-cancer-prevention-and-early-detection-what-is-cervical-cancer>. Accessed 07/20/2010, 2010.
3. Agency for Healthcare Research and Quality. Screening for Cervical Cancer: Recommendations and Rationale. Available at: <http://www.ahrq.gov/clinic/3rduspstf/cervcan/cervcanrr.htm#clinical>. Accessed 07/20/2010, 2010.
4. Hathaway JK, Pathak PK, Maney R. Is liquid-based pap testing affected by water-based lubricant?. *Obstetrics & Gynecology*. 2006;107:66-70.
5. Griffith WF, Stuart GS, Gluck KL, Heartwell SF. Vaginal speculum lubrication and its effects on cervical cytology and microbiology. *Contraception*. 2005;72:60-64.
6. Gilson M, Desai A, Cardoza-Favarato G, Vroman P, Thornton JA. Does gel affect cytology or comfort in the screening papanicolaou smear?. *Journal of the American Board of Family Medicine: JABFM*. 2006;19:340-344.
7. Harer WB, Valenzuela G, Jr, Lebo D. Lubrication of the vaginal introitus and speculum does not affect papanicolaou smears. *Obstetrics & Gynecology*. 2002;100:887-888.
8. Charoenkwan K, Ninunanahaeminda K, Khunamornpong S, Srisomboon J, Thorner PS. Effects of gel lubricant on cervical cytology. *Acta Cytol*. 2008;52:654-658.
9. Tavernier LA, Connor PD, Gates D. Water vs gel lubricant for cervical cytology specimens. *J Fam Pract*. 2003;52:701-704.
10. Amies AM, Miller L, Lee SK, Koutsky L. The effect of vaginal speculum lubrication on the rate of unsatisfactory cervical cytology diagnosis. *Obstetrics & Gynecology*. 2002;100:889-892.

TABLES

Table 1: Modified Jadad Score of Calculations

Jadad Score Calculation	
Item	Score
Was the study described as randomized (this includes words such as randomly, random, and randomization)?	0/1
Was the method used to generate the sequence of randomization described and appropriate (table of random numbers, computer-generated, etc)?	0/1
Was the study described as double blind?	0/1
Was the method of double blinding described and appropriate (identical placebo, active placebo, dummy, etc)?	0/1
Was there a description of withdrawals and dropouts? <i>Were patients who declined participation in the study described in the Methods section?</i>	0/1
Deduct one point if the method used to generate the sequence of randomization was described and it was inappropriate (patients were allocated alternately, or according to date of birth, hospital number, etc).	0/-1
Deduct one point if the study was described as double blind but the method of blinding was inappropriate (e.g., comparison of tablet vs. injection with no double dummy).	0/-1

Table 2: Characteristics of Included Studies

STUDY/ Year Published	Patients/ Population	Intervention	Comparison	Outcome(s)	Study Type	Jada d	Comments
Hathaway et al (2006)	Women undergoing routine pap smears at a Resident run clinic	Two samples collected. 0.5 ml of water-based lubricant was added to one of the samples after it was collected.	Compared to a control sample in each patient, and then compared to a control group	Results were identical in 185 women. They were similar in 180 women. Results were dissimilar in 15 women, with 11 of them showing clinically significant differences. One inadequate specimen in each group. No statistically significant difference between groups in recognizing bv, yeast infections or other pathology	RCT	5/5	Only study found that uses Thinprep as their pap collection. Study did not accurately describe in their methods section, how many samples were analyzed by one or by two pathologists. Would be difficult to replicate
Tavernier et al (2003)	Women who received Pap smears between 1995 and 1999 at a Resident run clinic	Medical records were analyzed for sample quality (whether it was a satisfactory sample, whether the sample was obscured by lubricant or blood)	Groups were compared between lubricant versus non-lubricant group and were also compared by fertility status (pregnant vs menopausal vs post-hysterectomy)	No statistically significant difference between groups who used lubricant and groups who didn't use lubricant.	Retrospective Cohort Study	N/A	Study was also measuring differences of pap results in each fertility status group. I did not include these statistics in the matrix
Amies et al (2002)	Women who were receiving a speculum examination at a Family Planning Clinic	Women either received speculum exams using tap water as a lubricant or gel lubricant	Gel lubricant group data was compared to water only lubricant groups	Unsatisfactory results, ASCUS, LSIL, HSIL, and AGCUS did not differ to the degree that they were statistically significant	RCT	5/5	
Charoenkwan et al (2008)	Women receiving regular Pap smears at a Family Planning Clinic	Women had water lubricated speculum exams. One sample was taken as usual. Gel lubricant was applied to the cervical os and a second cervical sample was taken	The control and experimental specimens were compared to one another. Groups were also analyzed according to their reproductive status	There was a higher incidence of unsatisfactory samples among the samples taken with lubricant. Most unsatisfactory results were due to not enough cells found in the sample. This was particularly true of lactating, post-partum and postmenopausal women. They also found that the gel was grossly and microscopically visible on the slide during analysis. However, there was consistency between samples when the samples were satisfactory.	Cohort Study	1/5	One LSIL and one ASCUS were missed in the gel lubricant group
Gilson et al (2006)	Females receiving routine annual gynecological examinations at an Air Force Family Practice Clinic	Women underwent two speculum exams. One using a dry speculum and one with gel lubricant applied to the speculum	Speculum with gel lubricant group was compared to dry speculum group	No difference in the amount of unsatisfactory slides was found between the gel vs. no gel groups.	RCT	5/5	Of note, there was no difference reported in level of discomfort between groups
Harer, Jr. et al (2002)	Women who were receiving speculum exams at a Women's Health Clinic	Women were randomly assigned to lubricant or water only groups. Lubricant groups had lubricant applied to the introitus and on the speculum	Lubricant group was compared to tap water only group	The researchers decided that in order to analyze the very low proportion of unsatisfactory slides they would have to include 10,000 patients in their study, so they closed it. Of note was the fact that no gross lubricant was seen on any of the slides that were analyzed.	RCT	2/5	
Griffith et al (2005)	Women who were getting regular speculum exams at a Family Planning Clinic.	Women were randomly assigned to either speculums with gel lubricant or speculums with water	Results from Gel lubricant group was compared to results from water lubricant group	No difference in the rate of unsatisfactory samples	RCT	5/5	Gel lubricant did not affect ability to detect Chlamydia or Gonorrhea.